2012-06-28

Barriers to Using Agile Software Development Practices within the Medical Device Industry

Martin McHugh
Technological University Dublin, martin.mchugh@tudublin.ie

Fergal McCaffery
Dundalk Institute of Technology, fergal.mccaffery@dkit.ie

Valentine Casey
Dundalk Institute of Technology, val.casey@dkit.ie

Barriers to using Agile Software Development Practices within the Medical Device Industry

Martin Mc Hugh, Fergal Mc Caffery and Valentine Casey

Regulated Software Research Group, Department of Computing and Mathematics
Dundalk Institute of Technology, Co. Louth Ireland
{Martin.McHugh, Fergal.McCaffrey, Val.Casey}@dkit.ie

Abstract

Non-safety critical software developers have been reaping the benefits of adopting agile practices for a number of years. However, developers of safety critical software often have concerns about adopting Agile practices. Through a literature review this research identified the perceived barriers to following agile practices when developing medical device software. A questionnaire based survey was also conducted with medical device software developers in Ireland to determine what the actual barriers are to adopting agile practices. In addition a comparison is performed between the perceived and actual barriers and the results are reported.

Keywords

Agile, Methods, Scrum, Medical Device, V-Model, Waterfall, Traditional Models, Plan Driven, XP, Mission Critical Software, Medical Device Software

1 Introduction

The popularity of agile practices is on the rise [1]. Agile practices appear to offer a "silver bullet" [2] for all of the problems associated with traditional plan driven software development lifecycles. A number of surveys have been completed which reinforce this believe [3, 4]. However, a large amount of research has been conducted into the success of adopting agile practices which is broad and does not expressly focus on specific domains within the software development industry i.e. safety critical software development.

Non-safety critical software is developed in accordance with a customer's requirements, but safety critical software must be developed in accordance with both a customer's requirements and national and/or international regulatory constraints. These regulatory constraints are dictated by the region in which it is planned to market the software, be it standalone or part of a hardware device. For example, if a medical device is to be marketed in the United States (US) it must be developed in accordance with the Food and Drug Administration (FDA) quality regulations, guidance documents and approved standards [5, 6]. Software developed for use within safety critical domains is typically developed in accordance with the Waterfall Model or V-Model software development lifecycles [6, 7]. These lifecycles are defined by upfront design with high importance placed upon the production of documentation [6]. These models produce the necessary deliverables required to achieve regulatory conformance.

Our research is focused on the development of software for use within the medical device domain. Regulatory requirements and development standards such as [8, 9] do not dictate the use of a particular lifecycle when developing medical device software. In fact they state that medical device software can be developed using a traditional, iterative and/or evolutionary approach. Despite this, medical device software developers typically develop software in accordance with the V-Model [7]. Whilst the V-Model produces necessary deliverables such as traceability between requirements and all stages of

the software development lifecycle [10] it is seen as being rigid and inflexible in the event of a change once development has begun [11].

This research was initiated by performing a literature review. One of the objectives of undertaking this literature review was the identification of the perceived barriers to adopting Agile practices when developing medical device software. Also as part of this research a questionnaire based survey was conducted amongst medical device software developers in Ireland. The aim of this survey was to evaluate the findings of the literature review and to learn what are the actual barriers to adopting agile practices when developing medical device software.

The remainder of this paper is structured as follows: Section 2 provides information as to our on-going research in this area and how this aspect of our work fits into this research. Section 3 details the perceived barriers to selecting and implementing agile practices when developing medical device software based on the results from our literature review. Section 4 outlines the approach taken by questionnaire based survey conducted amongst medical device manufacturers in Ireland. Section 5 provides the results of the survey and within section 6 a comparison is performed between the perceived barriers and the actual barriers to adopting Agile practices.

2 Research Objectives

As part of this on-going research the following research questions has been identified. This research is:

1. What are the issues associated with developing medical device software?
2. What are the issues with developing medical device software using a traditional software development lifecycle?
3. Which agile practices are suited to developing medical device software?
4. To what extent do existing medical device software development lifecycles need to be tailored to incorporate suitable agile practices?

The results from the research outlined in this paper will be used to help address the third research question. By identifying actual barriers to the adoption of agile practices specific practices can be discounted and the remaining agile practices can be evaluated for suitability. These research questions were formed following the completion of a literature review. This literature review began by broadly looking at generic software development lifecycles. The focus of the literature review moved to the development of safety critical software and then onto the development of software in the medical device industry. Following this phase of the literature review, research was conducted into agile software development. This involved examining mainstream methodologies such as Scrum and XP. Once this was completed we then focused upon the adoption of agile practices in the development of safety critical software. Finally, we considered the adoption of agile practices in the development of medical device software. This literature revealed a number of perceived barriers to adopting agile practices when developing medical device software.

Following the literature review a questionnaire based survey was conducted amongst medical device software developers in Ireland. The objective of this survey was to evaluate the findings of the literature review and to learn what the actual barriers to adopting agile practices are.

3 *Perceived Barriers to Agile Adoption*

As discussed in section 1, software developed for use in or as a medical device must meet the regulatory requirements of the region where the device is being marketed. As a result many of the perceived barriers to adopting agile practices in developing medical device software are associated with regulatory controls [12]. The focus of this research is the identification of the perceived barriers that have a direct impact on the development process of medical device software and the implementation of agile methods in this context. Additional barriers do exist, but a number of these are organisational barriers that do not have a direct impact on the development of medical device software. An example of such an organisational barrier is that Human Resource policies and processes do not cater for the requirements of an Agile team [13]. The literature review performed identified the following perceived barriers to the adoption of agile practices when developing medical device software.

The FDA General Principles of Software Validation (GPSV) [9] require manufacturers to explicitly document requirements prior to implementation and test procedures [14]. This would appear to be an apparent barrier to adopting agile practices as one of the fundamental principles of the agile Manifesto [15] is "*working software over comprehensive documentation*". Combined with this another central principle of agile software development is that requirements are fluid and changes in requirements can be easily accommodated and are even welcomed throughout a development project [16]. Without fully refining requirements prior to the beginning of a project the process of traceability can be difficult and traceability between requirements and all stages of development is required by the FDA [17].

As safety critical software such as medical device software can place patients, clinicians and third parties at potential risk, medical device software developers must perform adequate risk management activities to ensure the software they are developing is safe and reliable. Boehm and Turner [13] suggest that risk management activities can be a barrier to adopting agile practices as agile practices do not provide sufficient guidance as how to perform the necessary risk management activities.

Another perceived barrier to adopting agile practices is that software developed using agile practices is of a lower quality than software developed following traditional plan driven lifecycles [13]. As medical device software is safety critical it must be developed to the highest quality possible.

Agile methodologies such as XP recommend short releases with continuous feedback [18]. When developing medical device software it is not possible to release incomplete software and await feedback as the software must be fully tested and working before it is used in patient treatment [19].

An additional potential barrier to adopting agile practices in the development of both safety critical and non-safety critical software is the loss of management control. Agile methodologies recommend that development teams are self-organising. This process of self-organising teams removes some of the decision making powers from management [20]. This can result in a loss of management control and for agile practices to succeed organisational support is required [21].

4 Survey of Medical Device Software Developers in Ireland

In order to gain an understanding as to what the perceived barriers and actual barriers are to the adoption of agile practices we performed a questionnaire based survey with medical device software development organisations within Ireland. The literature review outlined in section 1 identified the perceived barriers to agile adoption and the survey results have been used to identify actual barriers to adopting agile practices when developing medical device software.

Within Ireland there are approximately 160 medical device manufacturers [22]. No research has been conducted to date to suggest how many of these organisations develop medical device software. As a result when determining sufficient sample size a decision was made to assume all of these organisation develop medical device software. Using sample size equations a sufficient sample size was determined as twenty organisations.

As a result of this the survey was conducted amongst twenty medical device software development organisations in Ireland with multiple responses from each organisation. These organisations ranged from small indigenous manufacturers to large multinational manufacturers. The devices produced by theses manufacturers range from Class I – Low Risk to Class III – High Risk[1] products. The primary goal of this survey was to gain a deeper insight into the medical device software development industry to further assist with our on-going research. Participants who took part in the survey included all levels of the development team and internal stakeholders such as managers and senior management.

The survey was developed in accordance with "*Introduction to Research Methods: A Practical Guide for Anyone Undertaking a Research Project*" and "*Designing Social Research*" [23, 24]. These books outline effective methods for constructing and undertaking a questionnaire based survey with the objective of achieving the maximum amount of relevant information. The survey began by asking participants what was their role in the organisation and how long they have been working in the medical device industry. The responses from these questions were used to qualify the expertise of the participants and to support the validity of their responses. In addition the fact that we received more than one response from each company enabled us to validate the quality of these responses from each company.

[1] This safety classification is defined by the European Council Medical Device Directive 93/42/EEC. Class I devices are deemed to pose low risk to patients, users and third parties and Class III devices are deemed to pose potentially life threatening risk to patients, users and third parties.

The first piece of significantly relevant information obtained by the survey was which software development lifecycle the organisations are following. As part of this on-going research, recommendations will be made as to how adopting agile practices can resolve problems associated with the current lifecycle being followed.

Following on from this question, participants were provided with a list of activities that are required to be completed in the development of safety critical software. Participants were requested to rate how much importance they place on each of these activities and to rate how effective they deem their organisation to be at performing these activities. The objective of this question was to understand which areas of safety critical software development are being performed most effectively. Again as part of this on-going research, information is being collected that will identify which stages of development pose the most difficulty to medical device software developers. This information will eventually be used to help answer research questions 1 and 2.

Finally participants were asked a series of questions relating to agile software development. Participants were provided with a list of potential agile barriers and asked to select which barriers they perceived would prevent the adoption of agile practices. The goal of this question was to evaluate the findings of the literature review. Participants where then asked what the actual barriers were within their own organisation to the adoption of agile methods. This question was used to establish what these barriers are and if commonality could be identified across organisations as to what actual barriers exist in relation to agile adoption. A barrier being defined as an actual barrier does not imply that the barrier is insurmountable. To maximise the amount of relevant information gathered, space was provided for the respondents to add additional information and/or comments for each question as they deemed necessary.

5 *Results of Survey*

As discussed, one of the objectives of the survey was to establish the actual barriers faced by medical device software developers. The results of the survey have also been used to evaluate the findings of the literature review in this context.

The following results are preliminary as this research is still on-going. The survey revealed that 100% of the respondents who are currently marketing medical device software are developing it for use in Europe. In addition, 79% of these are also developing medical device software for use in the US.

The survey identified that 50% of the organisations are developing software in accordance with the V-Model. An important finding was that another 25% of the organisations are developing medical device software in accordance with agile practices. The remaining 25% of organizations are developing software in accordance with other development lifecycles such as the Waterfall model.

As part of the survey, respondents were asked what they believe to be the perceived barriers to agile adoption. The survey revealed that 25% of respondents reported “Lack of Documentation” as a barrier to agile adoption. In addition 25% of respondents reported “Regulatory Compliance”, whilst 16% of respondents reported “Lack of Up-Front planning” and 17% of respondents reported “Insufficient coverage of risk management activities” as barriers to agile adoption. These results were consistent with the findings from the literature review.

Finally, respondents of the survey were asked what the actual barriers to adopting agile practices are. Of the respondents 50% reported “Lack of Experience”, 33% reported that having to change the existing lifecycle as a barrier to agile adoption, 16% reported “Management Opposed to Change “and 16% reported team size as a barrier to agile adoption. A further 17% reported that getting stakeholder buy in as a barrier and 17% reported the level of retraining required as another barrier to agile adoption.

6 *Comparison between Perceived and Actual Barriers*

Table 1 presents a list of the perceived barriers based on our literature review and the actual barriers to agile adoption when developing medical device software based on our survey results.

Table 1 Perceived and Actual Barriers to Agile adoption

Perceived Barriers	*Actual Barriers*
• Regulatory Control • In-sufficient coverage of Risk Management Activities • Requirements Management • Traceability issues • Loss of management control • Lower quality software	• Regulatory Control • In-sufficient coverage of Risk Management Activities • Lack of up-front planning • Lack of documentation • Management opposed to change • Team size • Modification of existing lifecycle • Lack of Experience using agile • Getting Stakeholder Buy In • Level of Retraining Required

It can be seen in table 1 that a number of the perceived barriers are also actual barriers to using agile practices when developing medical device software. An important point to emerge from our research is how requirements can be identified and successfully managed in the context of utilising agile practises. Regulatory bodies require medical device software developers to document requirements prior to development. These requirements are then used during the development stages to provide traceability. Agile principles dictate that requirements be fluid throughout a development project and this can be seen as a barrier as we have outlined in section 3.

However, regulatory bodies do recognise the acceptability of what can be termed an agile approach to requirements. The FDA GPSV states [9]:

> *"Most software development models will be iterative. This is likely to result in several versions of both the software requirement specification and the software design specification. All approved versions should be archived and controlled in accordance with established configuration management procedures"*.

This emerged from our detailed analysis of the relevant regulations, standards and guidance documents. This was not evident from the published academic literature in this area, in fact the opposite was the case as we have stated.

This provides an example of how the perceived barriers to agile adoption can be overcome. Further research will be undertaken to evaluate and determine how each of the other barriers identified can be addressed by employing specific agile practices or by integrating agile practices with a plan driven lifecycle.

7 Conclusions

A number of barriers to adopting agile practices when developing medical device software have been identified through a literature review and questionnaire based survey. Medical device software developers must develop software in accordance with regulatory requirements and as a result a number of the barriers to agile adoption are associated with the process of achieving regulatory conformance.

Regulatory bodies and medical device software development standards do not dictate the usage of a specific software development lifecycle for developing medical device software [8, 9] . Regulatory bodies have a set of deliverables which device manufacturers must deliver. Medical device software developers can develop software in accordance with agile practices once they provide the necessary deliverables. Research conducted by Rasmussen et al and Rottier et al [25, 26], identified that no single agile methodology could be strictly adhered to when developing medical device software as no single agile methodology provides sufficient coverage of all of the areas necessary to achieve regulatory conformance. However, Rasmussen et al and Rottier et al [25, 26] did identify that selectively choosing appropriate agile practices and integrating them with a plan driven lifecycle can reap the benefits of employing agile practices whilst still producing the necessary regulatory deliverables. This is an area we plan to investigate further as part of our on-going research.

Acknowledgements
This research is supported by the Science Foundation Ireland (SFI) Stokes Lectureship Programme, grant number 07/SK/I1299, the SFI Principal Investigator Programme, grant number 08/IN.1/I2030 (the funding of this project was awarded by Science Foundation Ireland under a co-funding initiative by the Irish Government and European Regional Development Fund), and supported in part by Lero - the Irish Software Engineering Research Centre (http://www.lero.ie) grant 10/CE/I1855

Author CVs

Martin Mc Hugh

Martin received his B.Sc. (Hons.) in Information Technology Management in 2005 and M.Sc. in Computer Science in 2009, from Dundalk Institute of Technology. He is now undertaking research for his Ph.D. in the area of software process improvement for medical devices with emphasis on the usage of agile practices when developing medical device software, as part of the Regulated Software Research Group in Dundalk Institute of Technology.

Fergal Mc Caffery

Dr Fergal Mc Caffery is the leader of the Regulated Software Research Group in Dundalk Institute of Technology and a member of Lero. He has been awarded Science Foundation Ireland funding through the Stokes Lectureship, Principal Investigator and CSET funding Programmes to research the area of software process improvement for the medical device domain. Additionally, he has received EU FP7 and Enterprise Ireland Commercialisation research funding to improve the effectiveness of embedded software development environments for the medical device industry.

Valentine Casey

Dr Val Casey is a Senior Researcher with the Regulated Software Research Group in Dundalk Institute of Technology. His previous roles include Senior Lecturer and Research Area Leader at Bournemouth University, Researcher with Lero - the Irish Software Engineering Research Centre at the University of Limerick where he also lectured. He has over 20 years' experience in the software industry. He has also provided consultancy services focusing on software process improvement and software testing in the financial and telecom sectors.

8 References

1. Conboy, K. and B. Fitzgerald, *Method and developer characteristics for effective agile method tailoring: A study of XP expert opinion.* ACM Trans. Softw. Eng. Methodol, 2010. **20**(1): p. 1-30.
2. Brooks, F.P., *No Silver Bullet Essence and Accidents of Software Engineering.* Computer, 1987. **20**(4): p. 10-19.
3. VersionOne, *State of Agile Survey - The Stage of Agile Development*. 2010.
4. http://www.ambysoft.com/surveys/agileFebruary2008.html#Downloads Accessed 04/10/2011
5. McCaffery, F., J. Burton, V. Casey, and A. Dorling, *Medical Device Industry: Software Process Improvement*, in *Encyclopedia of Software Engineering*, P. Laplanye, Editor. 2010, CRC Press Francis Taylor Group: London. p. 528-540.
6. Ge, X., R.F. Paige, and J.A. McDermid, *An Iterative Approach for Development of Safety-Critical Software and Safety Arguments*, in *Agile 2010*. 2010.
7. Bulska, K. and J. Gorski, *Applying Agile Practices to the development of Safety-Critical Software*, in *ICT Young 2011, Scientific Booklets of Faculty of Electronics, Telecommunications and Informatics*. 2011: Gdańsk University of Technology. p. 65-68.
8. AAMI, *ANSI/AAMI/IEC 62304, Medical device Software - Software life cycle processes*. 2006.
9. FDA, *General Principles of Software Validation: Final Guidance for Industry and FDA Staff*. 2002, *Centre for Devices and Radiological Health*.
10. McCaffery, F., V. Casey, M. Sivakumar, G. Coleman, P. Donnelly, and J. Burton, *Medical Device Software Traceability*, in *Software and Systems Traceability*. 2011, Springer-Verlag.
11. Munassar, N.M.A. and A. Govardhan, *A Comparison Between Five Models Of Software Engineering.* IJCSI International Journal of Computer Science Issues,, 2010. **7**(5): p. 94-101.
12. Mishra, S. and H.R. Weistroffer, *Issues with Incorporating Regulatory Compliance into Agile Development: A Critical Analysis*, in *Southern Association for Information Systems (SAIS)*. 2008.

13. Boehm, B. and R. Turner, *Management Challenges to Implementing Agile Processes in Traditional Development Organizations.* IEEE Software, 2005. **22**(5): p. 30-39.
14. Vogel, D., *Agile Methods:Most are not ready for prime time in medical device software design and development.* DesignFax Online, 2006(July 2006).
15. Fowler, M. and J. Highsmith, *The Agile Manifesto*, in *Software Development: The Lifecycle starts here*. 2001.
16. Boehm, B. and R. Turner, *Balancing Agility and Discipline: A Guide for the Perplexed*. 2003: Addison-Wesley.
17. Weiguo, L. and F. Xiaomin, *Software Development Practice for FDA-Compliant Medical Devices*, in *International Joint Conference on Computational Sciences and Optimization, 2009.* . 2009: Sanya, Hainan. p. 388 - 390.
18. Abrahamsson, P., O. Salo, J. Ronkainen, and J. Warsta, *Agile Software Development Methods - Review and Analysis*, in *ESPOO 2002*. 2002, VTT Publications.
19. FDA, *Title 21--Food and Drugs Chapter I --Food and Drug Administration Department of Health and Human Services subchapter h--Medical Devices part 820 Quality System Regulation*. 2007, *U.S. Department of Health and Human Services*.
20. Moe, N.B., T. Dingsoyr, and T. Dyba, *Understanding Self-Organizing Teams in Agile Software Development*, in *Conference on Software Engineering, 2008. ASWEC 2008. 19th Australian* 2008: Perth, Australia.
21. Salo, O. and P. Abrahamsson, *Integrating agile software development and software process improvement: a longitudinal case study*, in *International Symposium on Empirical Software Engineering* 2005.
22. McHugh, M., *Medical Device Sector in Ireland.* Network Enterprise Europe, 2010.
23. Dawson, C., *Introduction to Research Methods: A Practical Guide for Anyone Undertaking a Research Project*. 2009: How To Books Ltd; 4th Revised edition edition.
24. Blaikie, N., *Designing Social Research*. 2000, Cambridge: Policy Press.
25. Rasmussen, R., T. Hughes, J.R. Jenks, and J. Skach, *Adopting Agile in an FDA Regulated Environment*, in *Agile Conference, 2009. AGILE '09.* . 2009: Chicago, IL p. 151-155.
26. Rottier, P.A. and V. Rodrigues, *Agile Development in a Medical Device Company*, in *Agile, 2008. AGILE '08. Conference*. 2008.